

# NUR HIDAYAT, S.Farm., Apt.



## QA MANAGER | REGULATORY AFFAIRS EXPERT | REGISTERED PHARMACIST

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### PROFESSIONAL SUMMARY

A registered professional Pharmacist with over 11 years of extensive experience in the Pharmaceutical and Cosmetics industries, specializing in **Quality Assurance (QA), Regulatory Affairs, and GMP (CPOB/CPKB) Compliance**. Proven track record in leading internal/external audits, managing CAPA & deviation systems, validation master plans, and securing product marketing authorizations (NIE) from BPOM. Successfully guided GMP re-certification and streamlined the regulatory launch of numerous product lines into commercial markets.

### WORK EXPERIENCE

#### PT. Alamanda Global Health & PT. Belia Global Kosmedika

Oct 2024 – Present

##### *Quality Assurance Manager*

- Lead quality oversight and ensure strict regulatory compliance for contract manufacturing (maklon) of prominent cosmetic brands, including *Facetology, Scora, Dorskin, Gloow&Be, Honnete, and Junny*.
- Bear ultimate responsibility for reviewing batch manufacturing records comprehensively to ensure quality and compliance prior to authorizing official Product Release.
- Manage the product complaint handling system and direct thorough investigations of process deviations across raw material (RM), packaging material (PM), mixing, and filling stages.
- Control the execution of the Change Control System, production equipment calibration programs, and spearhead both internal and external corporate compliance audits.

#### PT. YSP Industries Indonesia (Subsidiary of YSP Industries Malaysia Sdn Bhd)

Mar 2018 – Sep 2024

##### *QA Manager / ex-QA Assistant Manager*

- Managed all site quality assurance functions, served as the primary Validation Master Plan (VMP) Owner, and meticulously maintained the factory Site Master File (SMF).
- **Regulatory Achievement:** Spearheaded audit preparation and successfully secured the **Renewal of GMP Certificate (CPOB)** from BPOM in 2022.
- Oversaw BMR Management by approving Master BMRs (Parts A, B, and C), dispensing protocols, finished product batch releases, and raw material/finished product Certificates of Analysis (CoA).
- Investigated critical quality issues utilizing System Incident Reports, Out of Specification (OOS) results, and product failures, enforcing proper Corrective and Preventive Actions (CAPA) and managing Product Recalls.
- Established, managed, and monitored the site Pharmacovigilance System, ensuring thorough documentation and expedited safety reporting to national regulatory authorities.

#### PT. YSP Industries Indonesia

Aug 2018 – Sep 2024

##### *Regulatory Affairs Pharmacist (Acting)*

- **Product Registration Achievement:** Successfully registered and obtained commercial Marketing Authorizations (NIE) from BPOM for **15 pharmaceutical products** between 2019–2021 (including Tretinoin Cream, Melomet Cream, Melaquin Cream, Betacylic Ointment, Dicoren Gel, Dermosol Cream, etc.).

- Managed the end-to-end dossier preparation for local product pre-registrations and registrations, executing online submissions via the BPOM New-AeRO system.
- Evaluated and submitted variation registrations for changes affecting registered products, and maintained highly professional external relations with BPOM officials.

#### PT. YSP Industries Indonesia

Apr 2016 – Sep 2017

##### QA Pharmacist

- Prepared Master BMR documentation adopted from the YSP Malaysia parent plant and structured BMR copies for routine manufacturing runs and process validation batches.
- Performed In-Process Quality Control (IPQC) monitoring within the production plant and completed final inspections prior to batch release protocols.
- Administered reference numbering and filing for System Incident Reports, Change Control protocols, qualification/validation data, and spearheaded site-wide SOP distribution and status follow-ups.

#### PT. Menarini Indria Laboratories

Sep 2017 – Feb 2018

##### QA Officer

- Managed the CAPA database by systematically tracking and inputting trends originating from HULS, deviations, environmental monitoring (EM) reports, internal audits, and risk assessments.
- Compiled the annual Product Quality Review (PQR) reports and coordinated the plant-wide monthly equipment calibration schedules.

#### PT. Ikapharmindo Putramas

Sep 2014 – Mar 2016

##### GMP Compliance Supervisor

- Conducted routine scheduled factory inspections across all operational sections, drafting specialized evaluation checklists and detailed audit/CAPA reports.
- Supervised the processing, inspection, and documentation of commercial products returned from the market and overseen the Change Control system for packaging materials.

## EDUCATION

#### Universitas Airlangga, Surabaya, Indonesia

2013 – 2014

Pharmacist Professional Program (Apt.)

#### Universitas Airlangga, Surabaya, Indonesia

2009 – 2013

Bachelor of Pharmacy (S.Farm.)

## SKILLS & CORE COMPETENCIES

|                                 |                                                                                                                                                                           |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Regulatory &amp; Quality</b> | CPOB / CPKB / GMP Compliance, BPOM Regulations & Product Registration, New-AeRO System, Document Control, Audit Management, CAPA & Deviation Handling, Pharmacovigilance. |
| <b>Instruments &amp; Tools</b>  | HPLC, Particle Counter, Microsoft Office Suite (Excel, Word, PowerPoint).                                                                                                 |
| <b>Languages</b>                | Indonesian (Native/Active), English (Professional Working Proficiency - Active Written, Passive Oral).                                                                    |

## INTERNSHIP & LEADERSHIP EXPERIENCE

- **Pharmacist Internship (PKPA):** Industrial placement in the QA Department of PT. Ikapharmindo Putramas (2014) & Community Pharmacy placement at PT. Kimia Farma Apotek (2013).

- **Head of Election Commission:** Student Executive Board (BEM) Faculty of Pharmacy, Universitas Airlangga (2012).
- **Regional Committee Coordinator (DKI Jakarta):** National Pharmacy Olympiad (2011).

## KEY ACHIEVEMENTS

- Successfully supported and led GMP (CPOB) Certification, resulting in PT YSP Industries Indonesia obtaining its initial GMP Certificate from BPOM in 2017
- Successfully managed regulatory registration activities and obtained Marketing Authorization Licenses (NIE) from BPOM for 3 pharmaceutical products in 2019 : Tretinon Cream, Melomet Cream and Melaquin Cream
- Successfully secured Marketing Authorization Licenses (NIE) from BPOM for 8 pharmaceutical products in 2020 : Betacylic Ointment, Dicoren Gel, Dermosol Cream, UO Cream, Tidact Gel, Fungizole Cream, Fusidasol Cream and Yucomy Cream
- Successfully secured Marketing Authorization Licenses (NIE) from BPOM for 8 pharmaceutical products in 2021 Econazine Cream, Virless Cream, B-Mycin Cream and Fustadin Cream
- Successfully led GMP renewal preparation and audit activities, resulting in PT YSP Industries Indonesian obtaining GMP Certificate Renewal from BPOM in 2022
- Developed, maintained and continuously improved Quality Management System (QMS) including CAPA, Change Control, Validation, Product Complaint Management, Product Recall, Pharmacovigilance and Internal Audit Program

